

Provenge® (sipuleucel-T) (Intravenous)

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I. Length of Authorization

Coverage will be provided for 3 doses only and may NOT be renewed.

II. Dosing Limits

Max Units (per dose and over time) [HCPCS Unit]:

- 1 billable unit every 14 days x 3 doses only

III. Initial Approval Criteria

Coverage is provided in the following conditions:

Prostate Cancer † ‡ 1-5,1e-8e

- Patient has castration-resistant metastatic disease; **AND**
 - Patient has an ECOG Performance status of 0-1; **AND**
 - Patient does not have liver metastases; **AND**
 - Must not be used in combination with chemotherapy; **AND**
 - Patient's life expectancy is estimated to be greater than 6 months; **AND**
 - Patient is asymptomatic or minimally symptomatic; **AND**
 - Patient has not previously received therapy with sipuleucel-T
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Preferred therapies and recommendations are determined by review of clinical evidence. NCCN category of recommendation is taken into account as a component of this review. Regimens deemed equally efficacious (i.e., those having the same NCCN categorization) are considered to be therapeutically equivalent.

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); Ⓢ Orphan Drug

IV. Renewal Criteria ¹

- Duration of authorization has not been exceeded (*refer to section I*)

V. Dosage/Administration ¹

| Indication | Dose |
|-----------------|--|
| Prostate Cancer | Infuse the contents of 1 pre-made bag (containing at least 50 million autologous CD54+ cells activated with PAP-GM-CSF) over 60 minutes. Administer 3 doses at approximately 2-week intervals. |

VI. Billing Code/Availability Information

HCPSC Code:

- Q2043 – Sipuleucel-T, minimum of 50 million autologous CD54+ cells activated with PAP-GM-CSF, including leukapheresis and all other preparatory procedures, per infusion
 - 1 billable unit = 1 dose (Code Price is per 250 mL)

NDC(s):

- Provenge suspension for injection: 30237-8900-xx

VII. References (STANDARD)

1. Provenge [package insert]. Seal Beach, CA; Dendreon Pharmaceuticals LLC; July 2017. Accessed March 2025.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for Sipuleucel-T. National Comprehensive Cancer Network, 2025. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed March 2025.
3. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for Prostate Cancer 1.2025. National Comprehensive Cancer Network, 2025. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National

Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed March 2025.

4. Kantoff PW, Higano CS, Shore ND, et al; IMPACT Study Investigators. Sipuleucel-T immunotherapy for castration-resistant prostate cancer. *N Engl J Med*. 2010 Jul 29;363(5):411-22. doi: 10.1056/NEJMoa1001294.
5. Small EJ, Schellhammer PF, Higano CS, et al. Placebo-controlled phase III trial of immunologic therapy with sipuleucel-T (APC8015) in patients with metastatic, asymptomatic hormone refractory prostate cancer. *J Clin Oncol*. 2006 Jul 1;24(19):3089-94. doi: 10.1200/JCO.2005.04.5252.
6. Noridian Healthcare Solutions, LLC. Local Coverage Article: Sipuleucel-T (Provenge®) – Coverage Criteria for Prostate Cancer – Clarification (A52926; A55719). Centers for Medicare & Medicaid Services, Inc. Updated on 11/16/2023 with effective date 10/19/2018. Accessed January 2025.
7. National Coverage Determination (NCD) for Autologous Cellular Immunotherapy Treatment (110.22). Centers for Medicare & Medicaid Services, Inc. Updated 01/06/2012 with effective date 06/30/2011. Accessed January 2025.

VIII. References (ENHANCED)

- 1e. Tannock IF, de Wit R, Berry WR, et al. Docetaxel plus Prednisone or Mitoxantrone plus Prednisone for Advanced Prostate Cancer. *N Engl J Med* 2004; 351:1502-1512.
- 2e. Berthold DR, Pond GR, Soban F, de Wit R, Eisenberger M, Tannock IF. Docetaxel plus prednisone or mitoxantrone plus prednisone for advanced prostate cancer: updated survival in the TAX 327 study. *J Clin Oncol*. 2008 Jan 10;26(2):242-5. doi: 10.1200/JCO.2007.12.4008.
- 3e. Ryan CJ, Smith MR, Fizazi K, et al. Abiraterone acetate plus prednisone versus placebo plus prednisone in chemotherapy-naïve men with metastatic castration-resistant prostate cancer (COU-AA-302): final overall survival analysis of a randomised, double-blind, placebo-controlled phase 3 study. *Lancet Oncol*. 2015 Feb;16(2):152-60. doi: 10.1016/S1470-2045(14)71205-7. Epub 2015 Jan 16.
- 4e. Beer TM, Armstrong AJ, Rathkopf DE, et al. Enzalutamide in Metastatic Prostate Cancer before Chemotherapy. *N Engl J Med*. 2014 Jul 31; 371(5): 424–433.
- 5e. Beer TM, Armstrong AJ, Rathkopf DE, et al. Enzalutamide in Men with Chemotherapy-naïve Metastatic Castration-resistant Prostate Cancer: Extended Analysis of the Phase 3 PREVAIL Study. *Eur Urol*. 2017 Feb; 71(2): 151–154.
- 6e. Fizazi K, Scher HI, Molina A, et al. Abiraterone acetate for treatment of metastatic castration-resistant prostate cancer: final overall survival analysis of the COU-AA-301 randomised, double-blind, placebo-controlled phase 3 study. *Lancet Oncol*. 2012 Oct;13(10):983-92. doi: 10.1016/S1470-2045(12)70379-0. Epub 2012 Sep 18.

- 7e. Scher H, Fizazi K, Saad F, et al. Increased Survival with Enzalutamide in Prostate Cancer after Chemotherapy. *N Engl J Med* 2012; 367:1187-1197.
- 8e. de Bono JS, Oudard S, Ozguroglu M, et al. Prednisone plus cabazitaxel or mitoxantrone for metastatic castration-resistant prostate cancer progressing after docetaxel treatment: a randomised open-label trial. *Lancet*. 2010 Oct 2;376(9747):1147-54. doi: 10.1016/S0140-6736(10)61389-X.
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- 10e. Corn PG, Heath EI, Zurita A, et al. Cabazitaxel plus carboplatin for the treatment of men with metastatic castration-resistant prostate cancers: a randomised, open-label, phase 1-2 trial [published correction appears in *Lancet Oncol*. 2020 Jan;21(1):e14]. *Lancet Oncol*. 2019;20(10):1432-1443. doi:10.1016/S1470-2045(19)30408-5
- 11e. Prime Therapeutics Management. Provenge Clinical Literature Review Analysis. Last updated March 2025. Accessed March 2025.

Appendix 1 – Covered Diagnosis Codes

| ICD-10 | ICD-10 Description |
|--------|--|
| C61 | Malignant neoplasm of prostate |
| Z85.46 | Personal history of malignant neoplasm of prostate |

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

The preceding information is intended for non-Medicare coverage determinations. Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents: <https://www.cms.gov/medicare-coverage-database/search.aspx>. Additional indications, including any preceding information, may be applied at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA):

| Medicare Part B Covered Diagnosis Codes | | |
|---|--------------------------|------------------------------------|
| Jurisdiction | NCD/LCA/LCD Document (s) | Contractor |
| All | 110.22 | All |
| F | A52926 | Noridian Healthcare Solutions, LLC |
| E | A55719 | Noridian Healthcare Solutions, LLC |

| Medicare Part B Administrative Contractor (MAC) Jurisdictions | | |
|---|---|---|
| Jurisdiction | Applicable State/US Territory | Contractor |
| E (1) | CA, HI, NV, AS, GU, CNMI | Noridian Healthcare Solutions, LLC |
| F (2 & 3) | AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ | Noridian Healthcare Solutions, LLC |
| 5 | KS, NE, IA, MO | Wisconsin Physicians Service Insurance Corp (WPS) |
| 6 | MN, WI, IL | National Government Services, Inc. (NGS) |
| H (4 & 7) | LA, AR, MS, TX, OK, CO, NM | Novitas Solutions, Inc. |
| 8 | MI, IN | Wisconsin Physicians Service Insurance Corp (WPS) |
| N (9) | FL, PR, VI | First Coast Service Options, Inc. |
| J (10) | TN, GA, AL | Palmetto GBA |
| M (11) | NC, SC, WV, VA (excluding below) | Palmetto GBA |
| L (12) | DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA) | Novitas Solutions, Inc. |
| K (13 & 14) | NY, CT, MA, RI, VT, ME, NH | National Government Services, Inc. (NGS) |
| 15 | KY, OH | CGS Administrators, LLC |